



OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Clarifying Current Roles and Responsibilities Described in the Coordinated Framework for the Regulation of Biotechnology

AGENCY: National Science and Technology Council

ACTION: Notice of Request for Public Comment

SUMMARY: The purpose of this Notice of Request for Public Comment is to solicit relevant comments that can assist in the finalization of the proposed update to the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework) to clarify the current roles and responsibilities of the EPA, FDA, and USDA consistent with the objectives described in the July 2, 2015 Memorandum issued by the Executive Office of the President.

DATES: Responses must be received by November 1, 2016 at 5:00 PM EDT to be considered.

ADDRESSES: You may submit information by either of the following methods (electronic is strongly preferred):

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Docket No. FDA-2015-N-3403. Follow the instructions for submitting information. Information submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged.
- *Mail:* National Science and Technology Council: Emerging Technologies Interagency Policy Coordination Committee, Office of Science and Technology Policy, 1650 Pennsylvania Avenue NW, Washington, DC 20504. If submitting a response by mail, please allow sufficient time for mail processing. Written/paper information, including attachments, will be posted to the docket unchanged. Responses must be received by the deadline to be considered.

Instructions: All submissions received must include Docket No. FDA-2015-N-3403 for Clarifying Current Roles and Responsibilities Described in the Coordinated Framework for the Regulation of Biotechnology; Request for Public Comment.

Disclaimer: All information received will be placed in the docket and will be publicly viewable at <http://www.regulations.gov>. Responses must be unclassified and should not contain any information that might be considered proprietary, confidential, or personally identifying (such as home address or social security number).

Responses to this Request for Public Comment will not be returned. The National Science and Technology Council is under no obligation to acknowledge receipt of the information received. No requests for a bid package or solicitation will be accepted; no bid package or solicitation exists. This Request for Public Comment is issued solely for information purposes and does not constitute a solicitation.

FOR FURTHER INFORMATION CONTACT: National Science and Technology Council: Emerging Technologies Interagency Policy Coordination Committee, Office of Science and Technology Policy, Executive Office of the President, Eisenhower Executive Office Building, 1650 Pennsylvania Ave., Washington DC 20504, Phone: 202-456-4444; Melissa M. Goldstein, Science@ostp.eop.gov; Online: <https://www.whitehouse.gov/webform/contact-emerging-technologies-interagency-policy-coordinating-committee-national-science-and>

SUPPLEMENTARY INFORMATION:

Background Information

While the current Federal regulatory system for biotechnology products effectively protects health and the environment, advances in science and technology have altered the product landscape in recent years. In addition, the complexity of the current regulatory system can make

it difficult for the public to understand how the safety of biotechnology products is evaluated and create challenges for small and mid-sized businesses navigating the regulatory process for these products.

To address these challenges, on July 2, 2015, the Executive Office of the President (EOP) issued a memorandum (July 2015 EOP Memorandum, Ref. 1) directing the primary agencies that regulate the products of biotechnology—the U.S. Environmental Protection Agency (EPA), the U.S. Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA)—to accomplish three tasks: (1) Update the Coordinated Framework for the Regulation of Biotechnology (51 FR 23302; June 26, 1986) (Ref. 2) by clarifying current roles and responsibilities; (2) Develop a long-term strategy to ensure that the Federal biotechnology regulatory system is equipped to efficiently assess the risks, if any, of the future products of biotechnology; and Commission an expert analysis of the future landscape of biotechnology products.

In directing the agencies to accomplish these three tasks, the Administration's goal is to ensure public confidence in the regulatory system and improve the transparency, predictability, coordination, and, ultimately, efficiency of the biotechnology regulatory system.

To accomplish the tasks described in the July 2015 EOP Memorandum, EPA, FDA, USDA and EOP formed a Biotechnology Working Group, which was established under the auspices of the Emerging Technologies Interagency Policy Coordination (ETIPC) Committee. Members of this working group spent the last 14 months performing a detailed analysis of the Federal system for regulation of biotechnology products, including by reviewing more than 900 comments that were submitted in response to a Request for Information that was posted last fall and interacting with members of the public at three public meetings that were held in different regions of the

country. These meetings included presentations describing agency-specific oversight of biotechnology products, discussions of case studies that provided concrete examples of how various biotechnology products might navigate the Federal biotechnology regulatory system, and breakout listening sessions with participants and representatives from the agencies. Transcripts of the public meetings, including comments received at the meetings, were placed in the public docket, along with all of the comments received in response to the Request for Information and a summary of individual input received during the breakout listening sessions.

On September 16, 2016, the Administration released the proposed update to the Coordinated Framework, available at:

https://www.whitehouse.gov/sites/default/files/microsites/ostp/biotech_coordinated_framework.pdf, and a *National Strategy for Modernizing the Regulatory System for Biotechnology Products*, available at:

https://www.whitehouse.gov/sites/default/files/microsites/ostp/biotech_national_strategy.pdf,

consistent with the first and second activities identified in the July 2015 EOP Memorandum. In addition, EPA, FDA, and USDA have commissioned an independent study by the National Academy of Sciences to satisfy the third of the three activities specified above

With respect to the proposed update to the Coordinated Framework, the July 2015 EOP Memorandum listed four areas to be addressed:

1. Clarify which biotechnology product areas are within the authority and responsibility of each agency;
2. Clarify the roles each agency plays for different product areas, particularly for those products that fall within the scope of multiple agencies, and how those roles relate to each other in the course of a regulatory assessment;

3. Clarify a standard mechanism for communication and, as appropriate, coordination among agencies, while they perform their respective regulatory functions, and for identifying agency designees responsible for this coordination function; and
4. Clarify the mechanism and timeline for regularly reviewing, and updating as appropriate, the Coordinated Framework to minimize delays, support innovation, protect health and the environment and promote the public trust in the regulatory systems for biotechnology products.

To accomplish the first task, the proposed update to the Coordinated Framework describes the types of biotechnology product areas regulated by the various components within each primary regulatory agency (*i.e.*, EPA, FDA, or USDA), organized by agency (see Section D of the proposed update to the Coordinated Framework). To accomplish the second task, the proposed update to the Coordinated Framework provides a table of responsibilities, organized by biotechnology product area (see Table 2. of the proposed update to the Coordinated Framework). The table describes the offices within each agency or agencies that may have regulatory responsibility for a given biotechnology product area, as well as relevant coordination across the agencies. To accomplish the third task, the proposed update to the Coordinated Framework describes memoranda of understanding (MOU) among the agencies, and the types of products and information that are covered within the scope of each MOU (see Section D 2 of the proposed update to the Coordinated Framework). To accomplish the final task, Section E of the proposed update to the Coordinated Framework discusses provisions for future review of the Coordinated Framework.

Information Requested

The National Science and Technology Council requests relevant comments that can inform the finalization of the proposed update to the Coordinated Framework by clarifying the current roles and responsibilities of the EPA, FDA, and USDA consistent with the objectives described in the July 2, 2015 EOP Memorandum.

Respondents are welcome to address one or more of the following questions in regard to the proposed update to the Coordinated Framework. Respondents are asked to identify which question(s) they are addressing.

1. What additional clarification could be provided regarding which biotechnology product areas are within the statutory authority and responsibility of each agency?
2. What additional clarification could be provided regarding the roles that each agency plays for different biotechnology product areas, particularly for those product areas that fall within the responsibility of multiple agencies, and how those roles relate to each other in the course of a regulatory assessment?
3. What additional clarification could be provided regarding communication and, as appropriate, coordination among agencies, while they perform their respective regulatory functions, and for identifying agency designees responsible for this coordination function?
4. What additional clarification could be provided regarding the mechanism and timeline for regularly reviewing, and updating as appropriate, the Coordinated Framework to minimize delays, support innovation, protect health and the environment and promote the public trust in the regulatory systems for biotechnology products?

References

These references are available electronically at <http://www.regulations.gov>. We have verified the Web site addresses, but we are not responsible for any subsequent changes to Web sites after this document publishes in the Federal Register.

1. Executive Office of the President. Office of Science and Technology Policy, Office of Management and Budget, United States Trade Representative, and Council on Environmental Quality. Modernizing the Regulatory System for Biotechnology Products, July 2, 2015. Available online at: https://www.whitehouse.gov/sites/default/files/microsites/ostp/modernizing_the_reg_system_for_biotech_products_memo_final.pdf.
2. Executive Office of the President. Office of Science and Technology Policy. Coordinated Framework for Regulation of Biotechnology. 51 FR 23302, June 26, 1986. Available online at: http://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf

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OSTP Billing Code – 3270-F6

[FR Doc. 2016-22802 Filed: 9/21/2016 8:45 am; Publication Date: 9/22/2016]